



4-17-06 IFW 1635/8

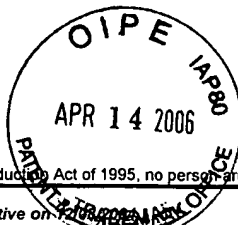
PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	09/802,376	
	Filing Date	March 9, 2001	
	First Named Inventor	Gary VAN NEST	
	Art Unit	1635	
	Examiner Name	J. Zara	
Total Number of Pages in This Submission	12 pages + 35 refs.	Attorney Docket Number	377882001700

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form + duplicate copy for fee processing - 2 pages	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Form PTO/SB/08a/b + copy - 6 pages
<input checked="" type="checkbox"/> Information Disclosure Statement (Supplemental) - 3 pages	<input type="checkbox"/> CD, Number of CD(s) _____	Thirty-five (35) references
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	MORRISON & FOERSTER LLP (Customer No. 25226)		
Signature			
Printed name	Debra J. Glaister		
Date	April 14, 2006	Reg. No.	33,888

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PTO/SB/17 (12-04v2)

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FEE TRANSMITTAL For FY 2005		Complete if Known	
Effective on 10/01/2005 Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).		Application Number	09/802,376
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Filing Date	March 9, 2001
		First Named Inventor	Gary VAN NEST
		Examiner Name	J. Zara
		Art Unit	1635
TOTAL AMOUNT OF PAYMENT		Attorney Docket No.	377882001700
(\$)		180.00	

METHOD OF PAYMENT (check all that apply)	
<input type="checkbox"/> Check	<input type="checkbox"/> Credit Card
<input type="checkbox"/> Money Order	<input type="checkbox"/> None
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<input checked="" type="checkbox"/> Deposit Account	Deposit Account Number: 03-1952
Deposit Account Name: Morrison & Foerster LLP	
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)	
<input checked="" type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee
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FEE CALCULATION							
1. BASIC FILING, SEARCH, AND EXAMINATION FEES							
	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fees Paid (\$)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	
2. EXCESS CLAIM FEES							
							Small Entity
Fee Description							Fee (\$)
Each claim over 20 (including Reissues)							50
Each independent claim over 3 (including Reissues)							200
Multiple dependent claims							360
							180
Total Claims							
57 - 66 = 0							
Extra Claims							
0 x 25 = 0.00							
Fee Paid (\$)							
Multiple Dependent Claims							
Fee (\$)							
180							
Fee Paid (\$)							
0.00							
Indep. Claims							
5 - 6 = 0							
Extra Claims							
0 x 100 = 0.00							
Fee Paid (\$)							
0.00							
3. APPLICATION SIZE FEE							
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
Total Sheets							
- 100 = _____ /50 _____ (round up to a whole number) x _____ = _____							
Extra Sheets							
Number of each additional 50 or fraction thereof							
Fee (\$)							
Fee Paid (\$)							
4. OTHER FEE(S)							
Fees Paid (\$)							
Non-English Specification, \$130 fee (no small entity discount)							
Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00							

SUBMITTED BY			
Signature		Registration No. (Attorney/Agent)	33,888
Name (Print/Type)	Debra J. Glaister	Telephone	(650) 813-5725
		Date	April 14, 2006

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Dated: April 14, 2006

Signature: *Georgina Matos*

(Georgina Matos)



Patent

Docket No. 377882001700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gary VAN NEST et al.

Serial No.: 09/802,376

Filing Date: March 9, 2001

For: IMMUNOMODULATORY
FORMULATIONS AND METHODS
FOR USE THEREOF

Examiner: J. Zara

Group Art Unit: 1635

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.

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- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
- ☐ A fee is required. A check in the amount of ___ is enclosed.
- ☒ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of ___ is enclosed.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other


Application Serial No. 09/802,376

Patent
Docket No. 377882001700

fees due in connection with the filing of this document to **Deposit Account No. 03-1952**
referencing 377882001700.

Dated: April 14, 2006

Respectfully submitted,

By 
Debra J. Glaister

Registration No.: 33,888
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
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ALTERNATIVE TO PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/802,376
				Filing Date	March 9, 2001
				First Named Inventor	Gary VAN NEST
				Art Unit	1635
				Examiner Name	J. Zara
Sheet	1	of	3	Attorney Docket Number	377882001700

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-2001/0046967-A1	11-29-2001	Van Nest	
	2.	US-2003/0022852-A1	01-30-2003	Nest et al.	
	3.	US-2003/0059773-A1	03-27-2003	Van Nest et al.	
	4.	US-2003/0129251-A1	07-10-2003	Van Nest et al.	
	5.	US-2003/0133988-A1	07-17-2003	Fearon et al.	
	6.	US-2003/0175731-A1	09-18-2003	Fearon et al.	
	7.	US-2003/0199466-A1	10-23-2003	Fearon et al.	
	8.	US-2003/0216340-A1	11-20-2003	Van Nest et al.	
	9.	US-2005/0037403-A1	02-17-2005	Krieg et al.	
	10.	US-5,770,434-A	06-23-1998	Huse	
	11.	US-6,086,901-A	07-11-2000	O'Hagan et al.	
	12.	US-6,194,388-B1	02-27-2001	Krieg et al.	
	13.	US-6,207,646-B1	03-27-2001	Krieg et al.	
	14.	US-6,214,806-B1	04-10-2001	Krieg et al.	
	15.	US-6,239,116-B1	05-29-2001	Krieg et al.	
	16.	US-6,306,405-B1	10-23-2001	O'Hagan et al.	
	17.	US-6,458,370-B1	10-01-2002	O'Hagan et al.	
	18.	US-6,534,062-B2	03-18-2003	Raz et al.	
	19.	US-6,544,518-B1	04-08-2003	Friede et al.	
	20.	US-6,558,670-B1	05-06-2003	Friede et al.	
	21.	US-6,610,661-B1	08-26-2003	Carson et al.	
	22.	US-6,855,492-B2	02-15-2005	O'Hagan et al.	
	23.	US-6,884,435-B1	04-26-2005	O'Hagan et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	24.	WO-00/54803-A2,A3	09-21-2000	Panacea Pharmaceuticals, LLC		
	25.	WO-00/61161-A2,A3	10-19-2000	University of Madras		
	26.	WO-01/22972-A2,A3	04-05-2001	University of Iowa Research Foundation et al.		
	27.	WO-01/22990-A2,A3	04-05-2001	Coley Pharmaceutical Group, Inc. et. al.		
	28.	WO-01/35991-A2,A3	05-25-2001	Dynavax Technologies Corporation		
	29.	WO-01/51500-A1	07-19-2001	The United States of America, represented by The Secretary, Department of Health and Human Services		
	30.	WO-01/54720-A1	08-02-2001	Cistem Biotechnologies GMBH		
	31.	WO-03/015816-A1	02-27-2003	Dynavax Technologies Corporation		

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/802,376
				Filing Date	March 9, 2001
				First Named Inventor	Gary VAN NEST
				Art Unit	1635
				Examiner Name	J. Zara
Sheet	2	of	3	Attorney Docket Number	377882001700

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	32.	Aderem, A. et al. (December 22, 2000). "How do you see CG?," <i>Cell</i> 103:993-996.		
	33.	Fearon, K. et al. (2003). "A Minimal Human Immunostimulatory CpG Motif That Potently Induces IFN- γ and IFN- α Production," <i>Eur. J. Immunol.</i> 33:2114-2122.		
	34.	Gursel, I. et al. (2001). "Sterically Stabilized Cationic Liposomes Improve the Uptake and Immunostimulatory Activity of CpG Oligonucleotides," <i>J. Immunology</i> 167:3324-3328.		
	35.	International Search Report mailed on February 11, 2002 for PCT Application No. PCT/US01/07848 filed on March 12, 2001, three pages.		
	36.	International Search Report mailed on August 27, 2002 for PCT Application No. PCT/US01/25364 filed on August 13, 2001, four pages.		
	37.	International Search Report mailed on February 11, 2002 for PCT Application No. PCT/US01/07843 filed on March 12, 2001, three pages.		
	38.	Kandimalla, E.R. et al. (2001). "Effect of Chemical Modifications of Cytosine and Guanine in a CpG-Motif of Oligonucleotides: Structure-Immunostimulatory Activity Relationships," <i>Bioorg. Med. Chem.</i> 9:807-813.		
	39.	Kato, D. et al. (2003). "The Design of Polymer Microcarrier Surfaces for Enhanced Cell Growth," <i>Biomaterials</i> 24:4253-4264.		
	40.	Kazzaz, J. et al. (2000). "Novel Anionic Microparticles are a Potent Adjuvant for the Induction of Cytotoxic T Lymphocytes Against Recombinant p55 gag From HIV-1," <i>J. Controlled Release</i> 67:347-356.		
	41.	Klinman, D.M. et al. (2004). "Use of CpG Oligodeoxynucleotides as Immune Adjuvants," <i>Immunological Reviews</i> 199:201-216.		
	42.	Kofler, N. et al. (1996). "Preparation and Characterization of Poly-(D,L-lactide-co-glycolide) and Poly-(L-lactic acid) Microspheres with Entrapped Pneumotropic Bacterial Antigens," <i>J. Immunological Methods</i> 192:25-35.		
	43.	Krieg, A.M. (2002). "CpG Motifs in Bacterial DNA and Their Immune Effects," <i>Annual Review Immunology</i> 20:709-760.		
	44.	Lefebvre, D.J. et al. (December 2003). "Th1-Directing Adjuvants Increase the Immunogenicity of Oligosaccharide-protein Conjugate Vaccines Related to <i>Streptococcus pneumoniae</i> Type 3," <i>Infection and Immunity</i> 71(12):6915-6920.		
	45.	Maloy, K.J. et al. (1994). "Induction of Mucosal and Systemic Immune Responses by Immunization with Ovalbumin Entrapped in Poly(lactide-co-glycolide) Microparticles," <i>Immunology</i> 81:661-667.		
	46.	Nellore, R.V. et al. (September-October 1992). "Evaluation of Biodegradable Microspheres as Vaccine Adjuvant for Hepatitis B Surface Antigen," <i>J. Parenteral Science and Technology</i> 46(5):176-180.		
	47.	O'Hagan, D.T. et al. (2000). "Microparticles in MF59, a Potent Adjuvant Combination for a Recombinant Protein Vaccine Against HIV-1," <i>Vaccine</i> 18:1793-1801.		
	48.	O'Hagan, D.T. et al. (2001). "Recent Developments in Adjuvants for Vaccines Against Infectious Diseases," <i>Biomolecular Engineering</i> 18:69-85.		
	49.	O'Hagan, D.T. et al. (2002). "Synergistic Adjuvant Activity of Immunostimulatory DNA and Oil/water Emulsions for Immunization with HIV p55 gag Antigen," <i>Vaccine</i> 20:3389-3398.		

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/802,376
				Filing Date	March 9, 2001
				First Named Inventor	Gary VAN NEST
				Art Unit	1635
				Examiner Name	J. Zara
Sheet	3	of	3	Attorney Docket Number	377882001700

50.	Plenat, F. (June 1996). "Animal Models of Antisense Oligonucleotides: Lessons for Use in Humans," <i>Molecular Medicine Today</i> 2(6):250-257.	
51.	Ponchel, G. et al. (1998). "Specific and Non-specific Bioadhesive Particulate Systems for Oral Delivery to the Gastrointestinal Tract," <i>Advanced Drug Delivery Reviews</i> 34:191-219.	
52.	Ryan, E.J. et al. (August 2001). "Immunomodulators and Delivery Systems for Vaccination by Mucosal Routes," <i>Trends in Biotechnology</i> 19(8):293-304.	
53.	Singh, M. et al. (November 1999). "Advances in Vaccine Adjuvants," <i>Nature Biotechnology</i> 17:1075-1081.	
54.	Singh, M. et al. (January 18, 2000). "Cationic Microparticles: A Potent Delivery System for DNA Vaccines," <i>PNAS</i> 97(2):811-816.	
55.	Uhlmann, E. et al. (2003). "Recent Advances in the Development of Immunostimulatory Oligonucleotides," <i>Current Opinion in Drug Discovery and Development</i> 6(2):204-217.	
56.	Van Uden, J. et al. (November 1999). "Immunostimulatory DNA and Applications to Allergic Disease," <i>Journal of Allergy and Clinical Immunology</i> 104(5):902-910.	
57.	Verthelyi, D. et al. (February 15, 2001). "Human Peripheral Blood Cells Differentially Recognize and Respond to Two Distinct CpG Motifs," <i>J. Immunol.</i> 166(4):2372-2377.	
58.	Weeratna, R.D. et al. (2000). "CpG DNA Induces Stronger Immune Responses with less Toxicity than Other Adjuvants," <i>Vaccine</i> 18:1755-1762.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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